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Attorneys for Plaintiff

PREVIVO GENETICS, LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PREVIVO GENETICS, LLC,

Plaintiff,

v.

KELLY PAGIDAS,

Defendant.

Case No.

**DECLARATORY JUDGMENT
COMPLAINT**

DEMAND FOR JURY TRIAL

Plaintiff Previvo Genetics, LLC (“Previvo” or “Plaintiff”) brings this Declaratory Judgment Complaint against defendant Kelly Pagidas (“Pagidas” or “Defendant”). This Declaratory Judgment Complaint relates to Previvo’s current efforts to resolve ongoing disputes between the parties regarding the inventorship of three of Previvo’s patents covering a uterine lavage system. Specifically, Previvo seeks a declaratory judgment that the inventors of its three patents are correctly named. Previvo alleges as follows:

NATURE OF THIS ACTION

1. This is an action seeking Declaratory Judgments that the inventors of United States Patent Nos. 9,282,995, 9,216,037, and 9,247,960, which are assigned to Previvo (collectively, “the Previvo patents”) are correctly named for these patents.

2. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, Title 35 of the United States Code.

THE PARTIES

3. Previvo is a corporation organized and existing under the laws of the state of California, with its principal place of business at 1340 S. De Anza Blvd., Suite 205, San Jose, CA 95129.

4. Previvo is the assignee of multiple patents, including the Previvo patents, and patent applications covering inventions pertaining to a uterine lavage system. Previvo is a start-up company formed for the purpose of commercializing innovative medical device products and medical procedures based on the inventions claimed in its patents.

5. Pagidas is a physician and clinician in the fields of reproductive endocrinology and infertility. Upon information and belief, Pagidas resides in Rhode Island at 9 Jason Drive, Lincoln, Rhode Island 02865. Upon information and belief, Pagidas works at the University of Louisville School of Medicine, Faculty Member, Department of Obstetrics, Gynecology & Women's Health, 550 S. Jackson St., Louisville, Kentucky, 40202. On information and belief, Pagidas works or has worked at Tufts Medical Center and/or Women and Infants Hospital of Rhode Island.

JURISDICTION

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. Venue is proper in this Court pursuant to 35 U.S.C. § 1391(b).

7. This Court has personal jurisdiction over Pagidas because Pagidas has availed herself of doing business in the state of California. Pagidas has at least minimum contacts with the state of California due to Pagidas' work on behalf of Previvo, a company located in California. Pagidas oversaw and/or participated in scientific testing and clinical trials related to Previvo's uterine lavage system for approximately two years, and received substantial reputational and professional benefits as a result of her work with Previvo.

FACTUAL BACKGROUND

Previvo Patents

8. Previvo is the owner by assignment of multiple patents and pending or abandoned patent applications, all of which disclose and/or claim inventions pertaining to a uterine lavage system. Uterine lavage may be performed to retrieve blastocysts prior to their implantation in the wall of the uterus. The retrieved blastocysts may be tested for genetic diseases or to determine the sex of the embryo. The retrieved blastocyst may thereafter be returned to the uterus for implantation and development into a fetus.

9. United States Patent No. 9,282,995 (“the ’995 patent”) issued from the earliest application in the family chain of these patents, U.S. Application No. 13/335,170, which was filed on December 22, 2011. The named inventors on the ’995 patent are Sandra Ann Carson and John E. Buster. A true and correct copy of the ’995 patent is attached as **Exhibit A** to this Complaint.

10. United States Patent No. 9,216,037 (“the ’037 patent”) issued from a continuation-in-part application of the ’995 patent, U.S. Application No. 13/924,520, which was filed on June 21, 2013. The named inventors on the ’037 patent are John E. Buster, Moses Cesario, and Steven Paul Woodard. A true and correct copy of the ’037 patent is attached as **Exhibit B** to this Complaint.

11. United States Patent No. 9,247,960 (“the ’960 patent”) issued from a divisional application of the ’995 patent, U.S. Application No. 14/250,240, which was filed on April 10, 2014. The named inventors on the ’960 patent are Sandra Ann Carson and John E. Buster. A true and correct copy of the ’960 patent is attached as **Exhibit C** to this Complaint.

12. None of the ’995, ’037, or ’960 patents names Pagidas as an inventor.

Relationship Between Previvo and Pagidas

13. The research and development activity described in the earliest-filed Previvo patent application (which issued as the ’995 patent) began in June, 2010.

14. Previvo was founded as a company during April, 2012.

15. Pagidas is and/or has been a professional colleague of John E. Buster (“J.E. Buster”), one of the named inventors of the Previvo patents. Through her association with J.E.

1 Buster, Pagidas began work on behalf of Previvo on or about April 26, 2013. Pagidas served as a
2 Principal Investigator on three Previvo studies relating to its uterine lavage system. From April
3 2013 through December 2014, she worked on a dose-ranging study involving GnRH antagonists,
4 entitled “Antagonist Luteolysis to Mitigate Ovarian Hyperstimulation following Gonadotropin
5 Induced Superovulation.” The GnRH antagonist study was performed pursuant to an agreement
6 between Previvo and Women and Infants Hospital of Rhode Island. From January 2014 until
7 about May 2015, she worked on two studies involving human subjects, including a uterine lavage
8 cycle test.

9 16. Pagidas also worked with Previvo between March 2014 and December 2014 on a
10 mouse blastocyst study relevant to the Previvo patents’ inventions. On information and belief,
11 Pagidas discussed certain aspects of design for the uterine lavage device with Previvo at various
12 times from March 2014 through August 2014. Upon J.E. Buster’s recommendation, Previvo
13 believed that Pagidas might become its Chief Scientist, but that never materialized. Pagidas did
14 not have a consulting agreement with Previvo, but on information and belief was being
15 compensated for her work by Women and Infants Hospital, and/or Tufts Medical Center, as the
16 prospective Principal Investigator developing protocols for the trials Previvo was intending to
17 conduct through Brown University, Women and Infants Hospital, and/or Tufts Medical Center.
18 On information and belief, over 50% of the hours she spent on Previvo matters were compensated
19 by Women and Infants Hospital, and/or Tufts Medical Center. Despite not having a formal
20 agreement with the company, Previvo was willing to compensate her for the reasonable value of
21 the services she provided to the company that had not already been compensated by her employer
22 in accordance with standard procedures designed to avoid any conflict of interest between
23 contracting parties. She refused to accept such reasonable offer of compensation and instead
24 demanded that she be paid for 100% of her time working with Previvo at an hourly consulting rate
25 that was far above what the company was paying to similar consultants.

26 17. Pagidas requested additional compensation and recognition from Previvo beginning
27 on or about February 15, 2015. Through March 2015, Previvo and Pagidas attempted to negotiate
28 a part-time employment agreement wherein Pagidas would be employed part-time by Previvo, but

1 were ultimately unable to agree on the terms of this agreement because she made demands for
2 compensation that were completely unreasonable for an early phase venture-backed start-up
3 company. From on or about March 31, 2015 to on or about May 15, 2015, Previvo and Pagidas
4 attempted to negotiate the terms of a consulting agreement wherein Pagidas would perform
5 consulting services for Previvo, but were ultimately unable to agree on the terms of this
6 agreement. Through the period of the above negotiations, Pagidas never raised the issue that she
7 had an inventorship dispute with the company with respect to any the Previvo patents.

8 18. Previvo formally terminated its association with Pagidas as of May 29, 2015.

9 ***Pagidas' Patent Inventorship Claims***

10 19. On May 15, 2015, Pagidas informed Previvo for the first time that she believed that
11 Previvo had filed patent applications containing Pagidas' purported inventions, yet omitted her as
12 an inventor.

13 20. On May 29, 2015, Steven K. Buster ("S.K. Buster"), the Chairman of the Board of
14 Previvo, responded to Pagidas that he had investigated Pagidas' claims of inventorship and further
15 that Previvo had confirmed that all its patents and applications correctly included only the named
16 inventors. S.K. Buster further requested that Pagidas identify the specific claims or inventions she
17 believed that she contributed. S.K. Buster further terminated Pagidas' involvement with Previvo's
18 scientific studies.

19 21. On June 15, 2015, Pagidas responded to S.K. Buster that she and J.E. Buster had
20 worked together collaboratively for the past five years. Pagidas stated that she believed that many
21 of her concepts were contained in Previvo's patents and patent applications. Pagidas did not
22 describe her contributions to Previvo's patents and applications and provided no written evidence
23 to substantiate her claims of inventorship.

24 22. On July 21, 2015, S.K. Buster responded to Pagidas by reiterating that, after
25 reviewing Pagidas' claims with the patent inventors and IP counsel, Previvo remained confident
26 that its patents' and applications' inventors were correctly named. For a second time, S.K. Buster
27 requested that Pagidas identify the specific inventions in the Previvo patents and applications that
28 she claimed to have conceived.

1 23. On November 3, 2015, Previvo was contacted by the Robins Kaplan law firm,
2 acting as counsel for Pagidas. Counsel for Pagidas reiterated her claims to inventorship on the
3 Previvo patents and applications despite again providing no written evidence to substantiate those
4 claims of inventorship. In addition, Pagidas, through counsel, challenged the inventive
5 contributions of the named inventors on Previvo's patents and applications, and noted that
6 incorrect inventorship could lead to invalidation of Previvo's patents.

7 24. On November 20, 2015, counsel for Pagidas discussed with counsel for Previvo her
8 alleged inventive concepts that were included in Previvo's patents and applications. Pagidas'
9 counsel asserted that certain aspects of the uterine lavage device and associated medical
10 procedures had been contributed by Pagidas. Pagidas' counsel stated that Pagidas' contributions
11 were present in certain claims in the publications of two Previvo patents – namely, the '995 patent
12 and the '960 patent.

13 25. The '995 patent was filed on December 22, 2011, well before Pagidas began her
14 relationship with the company in February 2013. The '960 patent issued from a divisional
15 application of the '995 patent and therefore contains no new subject matter different from the '995
16 patent to which it claims priority, again well before Pagidas started her work with Previvo.

17 26. On January 11, 2016, Previvo's counsel reiterated Previvo's confidence in the
18 correct naming of inventors of its patent portfolio.

19 27. On February 25, 2016, counsel for Pagidas informed Previvo that she would be
20 willing to withdraw her claim of inventorship of the Previvo patents in exchange for various
21 concessions, including a royalty percentage of Previvo's future sales and full authorship rights to
22 any Previvo publications related to its lavage technology. Pagidas has continued to inquire,
23 through counsel, whether Previvo will agree to pay Pagidas a royalty in exchange for Pagidas'
24 dropping her inventorship claim and assigning her rights in the Previvo patents to Previvo.

25 28. Previvo's ownership of the Previvo patents is critical to its business and market
26 position. Pagidas' continued stance that she should be named as a co-inventor of the Previvo
27 patents, and that she is entitled to compensation in exchange for the assignment of her ownership
28 rights, casts a cloud of uncertainty over the ownership of the Previvo patents. Indeed, Previvo's

rights in its patents could be adversely affected if Pagidas herself were to bring a declaratory judgment action pursuant to 35 U.S.C. § 256 to correct their inventorship. Previvo believes that, because Pagidas has repeatedly asserted her inventorship claims and retained counsel to negotiate her ownership rights in Previvo's patents, Pagidas may ultimately choose to bring such an action.

29. Under all the circumstances alleged herein, an actual and substantial controversy therefore exists between Previvo and Pagidas of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the inventorship and thus ownership of U.S. Patent Nos. 9,282,995, 9,216,037, and 9,247,960.

30. The Court may and should exercise its broad discretion to adjudicate this action under the Declaratory Judgment Act. There is no better or more effective remedy or forum for resolving the present controversies between the parties. Such adjudication will serve the underlying purposes of the Declaratory Judgment Act by resolving legal disputes between Previvo and Pagidas regarding their respective legal rights to manufacture and sell inventions related to the uterine lavage system claimed in Previvo's patents. This dispute should be resolved efficiently and economically in this action, deciding the controversies between the parties with certainty, completeness and finality.

Claim for Relief
DECLARATORY JUDGMENT OF CORRECT
INVENTORSHIP OF THE PREVIVO PATENTS

31. Previvo realleges and incorporates by reference the averments pled in the preceding paragraphs of this Complaint.

32. An actual and justiciable controversy exists between Previvo and Pagidas regarding the inventorship of the Previvo patents under 35 U.S.C. § 256.

33. The named inventors on U.S. Patent Nos. 9,282,995, 9,216,037, and 9,247,960 are the true, correct, and complete set of inventors for each patented invention claimed therein.

34. Previvo is entitled to a judgment declaring that the named inventors on U.S. Patent Nos. 9,282,995, 9,216,037, and 9,247,960 are the true, correct, and complete inventors for each patented invention claimed therein.

PRAYER FOR RELIEF

WHEREFORE, Previvo respectfully prays for entry of judgment as follows:

(a) Declaring the named inventors on U.S. Patent Nos. 9,282,995, 9,216,037, and 9,247,960 are the true, correct, and complete inventors for each patented invention claimed therein.

(b) Finding this to be an “exceptional case” within the meaning of 35 U.S.C. § 285 and awarding to Previvo its attorneys’ fees and costs incurred in this action; and

(c) Awarding Previvo such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Previvo demands a trial by jury of any and all issues on which a trial by jury is available under applicable law.

Dated: April 26, 2016

FISH & RICHARDSON P.C.

By: /s/ James Huguenin-Love
James Huguenin-Love

Attorneys for Plaintiff
PREVIVO GENETICS, LLC